

REMARKS

This amendment is in response to the Office Action, dated June 28, 2006 ("Office Action"). Following entry of the present amendment, claims 1, 110-200, and 204-205 are pending; claims 146, 153, 184, 187, 191, 197 and 200 having been amended; claims 168-176 having been withdrawn (claims 1, 110-167, 177-183, 186, 188-190, 192-199 having previously been withdrawn); claims 201-203 having been canceled (claims 2-109 having previously been canceled), and claims 204 and 205 having been added by virtue of the present amendment. No new matter has been added. Allowance and reconsideration of the application in view of Applicants' amendment and the ensuing remarks are respectfully requested.

The specification has been amended to recite that this application is a "continuation" of U.S. Patent Application Serial no. 09/491,500, and that U.S. Patent Application Serial No. 09/491,500 is now U.S. Patent No. 7,018,979.

Claims 153 and 197 have been amended to recite that the medicant is a N-methyl-D-aspartate (NMDA) "receptor antagonist". Support for this amendment may be found on page 13 of the specification.

Claims 146 and 184 have been amended to recite that the agonist of a calcium-activated potassium channel "is selected from the group consisting of NS 1619, 1-EBIO, guanylyl cyclase activating protein and combinations thereof." Support for this amendment may be found throughout the specification; for example, at page 10.

Claims 187 and 191 have been amended to correct grammatical errors.

Claim 200 has been amended to recite that the kit also comprises a "medicant" for delivery to an abnormal brain region and that the agonist "is selected from the group consisting of NS-1619, 1-EBIO, guanylyl cyclase activating protein and combinations thereof." Support for this amendment may be found throughout the specification; for example, at pages 10 and 15.

New claim 204 has been added and is similar to amended claim 184 except that the agonist is "other than a metalloporphyrin." Support may be found throughout the specification; for example, at page 10.

New claim 205 has been added and is similar to amended claim 200 except that the agonist is "other than a metalloporphyrin." Support may be found throughout the specification; for example, at pages 10 and 15.

Examiner withdrew claims 168-176 from consideration for being drawn to non-elected subject matter.

Examiner rejected claims 184, 185, 187 and 191 under 35 U.S.C. §102(b) as being anticipated by Novogrodsky *et al.* (J. Immunol. 143: 3981-3987, 1989). Examiner found that Novogrodsky *et al.* taught a culture of peripheral blood mononuclear cells comprising IL-2 and Zn protoporphyrin or Sn protoporphyrin. The culture was considered by the Examiner as a pharmaceutically acceptable solution unless evidence is submitted to the contrary. Examiner noted that protoporphyrins are calcium activated potassium channel agonists. Applicants respectfully traverse this rejection.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131 (citing Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987)).

Claim 184 as amended recites that the agonist of a calcium-activated potassium channel "is selected from the group consisting of NS-1619, 1-EBIO, guanylyl cyclase activating protein and combinations thereof." As such, the disclosure of Novogrodsky *et al.* regarding a culture of peripheral blood mononuclear cells comprising IL-2 and Zn protoporphyrin or Sn protoporphyrin does not anticipate amended claims 184 and claims that depend therefrom. Thus, Applicants respectfully request reconsideration and withdrawal of this rejection with respect to claims 184, 185, 187 and 191.

Examiner rejected claims 200-203 under 35 U.S.C. §103(a) as being obvious over the references as described below.

Claims 200-201 were allegedly unpatentable over Veltkamp *et al.* (Stroke 29: 837-843, 1998). Examiner found that Veltkamp *et al.* taught "methods for assaying the effects of NS-1619 on the vascular response to NMDA after hypoxia and ischemia."

Although Veltkamp *et al.* did not teach organizing NS-1619 and NMDA into a kit, it would have been obvious to one skilled in the art to organize the agents because one skilled in the art would appreciate that “organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.” Examiner also noted that “instructions for use” did not impart patentable weight because application of printed matter to an old article cannot render the article patentable. With respect to canceled claim 201, this rejection is rendered moot. With respect to amended claim 200, Applicants respectfully traverse this rejection.

Claims 200 and 202 were allegedly unpatentable over Devor *et al.* (Am. J. Physiol. 271(5): L775-84, 1996). Examiner found that Devor *et al.* “evaluated the effects of 1-EBIO and charybdotoxin on chloride ion secretion in T82 monolayers.” Examiner also found that the kit would have been obvious for the same reasons set forth above. With respect to canceled claim 202, this rejection is rendered moot. With respect to amended claim 200, Applicants respectfully traverse this rejection.

Claims 200 and 203 were allegedly unpatentable over Novogrodsky *et al.* Examiner found that Novogrodsky *et al.* taught a culture of peripheral blood mononuclear cells comprising IL-2 and Zn protoporphyrin or Sn protoporphyrin. The culture was considered by the Examiner as a pharmaceutically acceptable solution. Examiner also found that the kit would have been obvious for the same reasons set forth above. Applicants respectfully traverse this rejection. With respect to canceled claim 203, this rejection is rendered moot. With respect to amended claim 200, Applicants respectfully traverse this rejection.

Three criteria must be met to establish a *prima facie* case of obviousness: (1) “there must be some suggestion or motivation . . . to combine reference teachings,” (2) “there must be a reasonable expectation of success,” and (3) the prior art references “must teach or suggest all the claim limitations.” MPEP § 2142 (emphasis added). Moreover, “[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure.” *Id.* (citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); emphasis added).

Applicants respectfully submit that Examiner's obviousness rejection of Claim 200 is not appropriate as none of the references teach the use of the kit or the components of the kit to deliver a medicant to an abnormal brain region. Further, claim 200 has been amended to recite that the kit also comprises a "medicant" for delivery to an abnormal brain region. Thus, even assuming that the use of the references are appropriate, which Applicants in no way concede, Applicants respectfully submit that Veltkamp *et al.*, Devor *et al.*, or Novogrodsky *et al* do not teach or suggest each element of their invention as claimed, and thus cannot render it obvious.

Applicants note that NMDA receptor antagonist is listed as a medicant that may be administered in accordance with an embodiment of the present invention. Thus, while Veltkamp *et al.* described the use of NMDA and NS-1619, Veltkamp *et al.* did not describe the use of NMDA receptor antagonist with NS-1619. As described in the specification at page 13, a NMDA *receptor antagonist* is among possible medicants that may be used in conjunction with NS-1619.

Applicants further note that charybdotoxin is an inhibitor of 1-EBIO (see Devor *et al.*, page L775), which would defeat the purpose of administering 1-EBIO to selectively deliver the medicant to the abnormal brain region. Thus, Claim 200 does not contemplate using charybdotoxin as a medicant.

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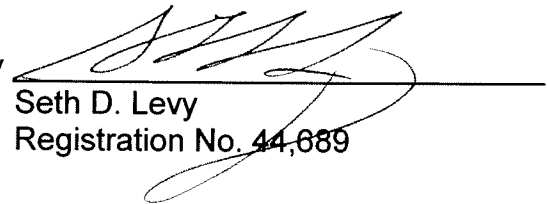
All of the claims remaining in the application are now believed to be allowable.
Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact
the undersigned at (213) 633-6869.

Respectfully submitted,

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